Statement on Signing the Food and Drug Administration Modernization Act of 1997

November 21, 1997

I am pleased to sign into law S. 830, the "Food and Drug Administration Modernization Act of 1997." This bipartisan legislation culminates several years of work by my Administration and the Congress on steps to streamline and rationalize the process by which the Food and Drug Administration (FDA) approves new drugs and medical devices, while ensuring that these products, on which the American people rely, are safe and effective. The Act represents the most comprehensive reform of our Nation's drug, medical device, and food laws in decades. I believe that it is a good compromise on a difficult set of issues and am pleased that the Congress and my Administration were able to work through these issues and enact a bipartisan bill. Most importantly, I am pleased that S. 830 addresses my key concern that any FDA legislation maintain our high standards to protect the American people from dangerous drugs, devices, and foods.

This legislation will extend through Fiscal Year 2002, the Prescription Drug User Fee Act, which requires drug companies to help underwrite the cost of FDA reviews of their products' safety and efficacy. This measure has enabled the FDA to eliminate backlogs and significantly shorten the review time of new human drug applications without compromising quality standards. Supported by the drug industry, the Prescription Drug User Fee Act illustrates the true benefits of a public-private partnership.

Certainly, FDA reform did not start with this bill. The Vice President has been working on reforming and reinventing the FDA since 1993. This bill codifies many of the reforms proposed by the Vice President's Reinventing Government Initiative. For example, it modernizes the regulations of biological products, eliminates the batch certification and monograph requirements for insulin and antibiotics, and streamlines the approval process for drug manufacturing changes. This Act also codifies reforms proposed by the FDA's Center for Devices and Radiological Health that will significantly improve both the rigor and timeliness of its premarket review of medical devices.

Notably, S. 830 will expand FDA's current program to streamline the filing and approval of new therapies for serious or life-threatening conditions. It will also codify FDA regulations and practices designed to ensure that patients will have access to therapies for serious and life-threatening conditions before they are approved for marketing. The Act requires the Department of Health and Human Services to establish a databank, providing information to the public on clinical trials of experimental treatments for serious and life-threatening conditions.

In addition, S. 830 includes a provision that eliminates certain health information dissemination restrictions, while maintaining public health protections. For example, product sponsors, manufacturers, or distributors will now be permitted to furnish to health professionals, providers, and others, peer-reviewed journal articles on an "off-label" use of an approved or cleared drug or device, so long as the manufacturers commit to completing the research needed to approve such use and meet other specified conditions. Drug manufacturers will also be able to give cost data to health maintenance organizations and other institutional purchasers of prescription drugs, so long as it is based on competent and reliable scientific evidence. The Act will also resolve the issue of pharmacy compounding—the process of making customized medicines—so that legitimate pharmacy compounding is allowed, while the manufacture of unapproved drugs is not.

While I am satisfied with the resolution of the issues in this legislation, I am also

pleased that the Congress included sunsets to certain of the Act's provisions so that, at the appropriate time, we can evaluate whether the proper compromises were reached. As FDA reform did not start with this bill, it will not end with this bill. Even with the streamlining provided in S. 830, the FDA will continue to face the challenge of fulfilling its many responsibilities and requirements within available resources. The Vice President and I look forward to continuing our work with patient groups, industry, and the Congress to make sure that the FDA is meeting the challenges of the future and providing safe and effective products to all Americans.

William J. Clinton

The White House,
November 21, 1997.

NOTE: S. 830, approved November 21, was assigned Public Law No. 105–115. This item was not received in time for publication in the appropriate issue.

Proclamation 7053—National Farm-City Week, 1997

November 21, 1997

By the President of the United States of America

A Proclamation

When Americans sit down to a meal each day, we sometimes take for granted the quality and variety of the food we eat. Our grocery stores, supermarkets, and restaurants offer us an enormous volume and selection of fruits, vegetables, meats, dairy products, and other food items, but we too often forget the hardworking men and women whose skill and effort put that food on our tables.

Strengthening our economy and providing food for people around the world, American agriculture is a leading global industry and a source of pride for our Nation. While producing an abundance of safe and affordable food and fiber, America's farmers and ranchers also provide a rich source of jobs in the United States. American agriculture employs more than 21 million people today, and agriculture-related industries continue to expand, pumping a trillion dollars into the American economy each year.

During the earliest days of our Nation, most of the crops farmers grew were used to feed their families or local consumers. Today, through advances in technology and marketing and through partnerships with agribusiness industries, research scientists, carriers, shippers, and retail distributors, America's farmers produce enough food and fiber to help meet the needs of people around the globe.

This week, as Americans gather with family and friends around the dinner table to give thanks for their many blessings, it is fitting that we count amount those blessings the vital farm-city partnerships that have done so much to improve the quality of our lives. Rural and urban communities, working together to make the most of America's rich agricultural resources, continue to contribute immensely to the health and well-being of our people and to the vigor of our national economy.

Now, Therefore, I, William J. Clinton, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim November 21 through November 27, 1997, as National Farm-City Week. I call upon citizens in urban and rural areas throughout the Nation to acknowledge and celebrate the achievements of all those who, working together, produce an abundance of agricultural products that strengthen and enrich our country.

In Witness Whereof, I have hereunto set my hand this twenty-first day of November, in the year of our Lord nineteen hundred and ninety-seven, and of the Independence of the United States of America the two hundred and twenty-second.

William J. Clinton

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